PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Appellant: Smith, S.	Examiner: Ganesan, Suba
Application No.: 10/630,562	Group Art Unit: 3774
Filed: July 30, 2003	Docket: 760-12 DIV/CON/RCE
For: HELICALLY FORMED STENT/GRAFT ASSEMBLY	Dated: January 9, 2009

Confirmation No.: 8643

Certificate of EFS-Web Transmission
I hereby certify that this correspondence is being transmitted to the U.S. Patent and Trademark Office via the Office's electronic filing system.
Dated: January 9, 2009
Signature: Jillian J. Romero

Mail Stop Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

APPEAL BRIEF PURSUANT TO 37 C.F.R. §41.37

Sir:

The Appellant has appealed the Examiner's Final Rejection of Claims 1, 3, 6-8, 12 and 13 dated July 9, 2008. This Appeal Brief is submitted in accordance with the provisions of 37 C.F.R. §41.37. As required by 37 C.F.R. §41.37(a)(2), please charge Deposit Account No. 08-2461 the requisite fee of $540.00 for submitting this Appeal Brief. If additional fees are required, please charge Deposit Account No. 08-2461. The Appellant has filed a timely Notice of Appeal on October 8, 2008 with a Pre-Appeal Brief Request for Review. A Notice of Panel Decision from Pre-Appeal Brief Review was mailed December 9, 2008, thus making this Appeal Brief due January 9, 2009. This Appeal Brief is being filed in support of the Notice of Appeal.

I. Real Party In Interest

The real party in interest is Boston Scientific Scimed, Inc., the assignee of the entire right, title and interest in and to Application No. 10/630,562.

II. Related Appeals and Interferences

No related appeals or interferences are known to the Appellants or the Appellants' legal representative which will directly affect or be directly affected by or have bearing on the Board's decision in this appeal.

III. Status of Claims

Claims 1-13 are presently pending in the application; claims 2, 4, 5 and 9-11 are withdrawn; and claims 1, 3, 6-8, 12 and 13 stand as being finally rejected. These rejected claims, i.e., claims 1, 3, 6-8, 12 and 13, are being appealed.

IV. Status of Amendments

In response to the final rejection mailed July 25, 2007, a Notice of Appeal was filed on October 8, 2008 without further amendments or arguments. In addition, no further amendments have been presented after the filing of this appeal.

V. Summary of Claimed Subject Matter

The present invention, as set forth in independent **claim 1**, is directed a stent/graft composite device (158, Fig. 12; 168, Fig. 18). (Specification, paragraph 0072, lines 1-3;

paragraph 0075, lines 4-6). The stent/graft composite device (158 in Fig. 12; 168 in Fig. 18) is formed from a flat preformed planar strip and stent assembly (148 in Fig. 10; 162 in Fig. 16). (Specification, paragraph 0072, lines 1-3; paragraph 0075, lines 4-6).

The flat preformed planar strip and stent assembly (148 in Fig. 10; 162 in Fig. 16) includes an elongate preformed planar strip of polymeric graft material (150 in Fig. 10; 164 in Fig. 16). (Specification, paragraph 0072, lines 1-3; paragraph 0075, lines 4-6). The elongate preformed planar strip of polymeric graft material (150 in Fig. 10; 164 in Fig. 16) is a non-textile planar strip of polymeric graft material. (Specification, paragraph 0084; Abstract, page 21).

The elongate preformed non-textile planar strip of polymeric graft material (150 in Fig. 10; 164 in Fig. 16) includes a first exterior surface (156 in Fig. 11; bottom surface of 164 in Fig. 17) and a second opposed luminal surface (154, Figs. 10 and 11; top surface of 164 in Figs. 16 and 17). (Specification, paragraph 0071, lines 3-4; paragraph 0075, lines 3-4). A planar stent (152 in Fig. 10; 166 in Fig. 16) is attached onto one of the opposed flat exterior (156 in Fig. 11; bottom surface of 164 in Fig. 17) or luminal (154, Figs. 10 and 11; top surface of 164 in Figs. 16 and 17) surfaces of the strip (150 in Fig. 10; 164 in Fig. 16) to form the flat strip assembly (148 in Fig. 10; 162 in Fig. 16). (Specification, paragraph 0071; paragraph 0075). The strip assembly (148 in Fig. 10; 162 in Fig. 16) is helically wound into a continuous tubular structure (158 in Fig. 12; 168 in Fig. 18). (Specification, paragraph 0072, lines 1-3; paragraph 0075).

VI. Grounds of Rejection to be Reviewed on Appeal

The following grounds of rejection are to be reviewed on this Appeal:

I. Whether claims 1, 3, 6-8, 12 and 13 are unpatentable under 35 U.S.C. §103(a) by U.S. Patent No. 6,352,561 to Leopold et al. in view of U.S. Patent No. 6,165,210 to Lau et al.?

VII. Argument

I. Rejection under 35 U.S.C. §103(a) by U.S. Patent No. 6,352,561 to Leopold et al. in view of U.S. Patent No. 6,165,210 to Lau et al.

Claims 1, 3, 6-8, 12 and 13

Leopold is directed to a stent-graft 106. (Leopold, column 6, lines 37-38; FIG. 3). The stent-graft 106 of Leopold includes a stent 126, a luminal graft 124 and an outer covering or tape member 128. (Leopold, column 9, lines 9-15). The stent 126 is formed by helically winding a wire around a mandrel. (Leopold, column 10, lines 63-65). Leopold then specifically teaches that the helically wound wire is heated while the wire is on the mandrel to set the shape, e.g.., tubular stent shape, of the so-formed stent. (Leopold, column 10, lines 65-67). Thus, Leopold specifically teaches that its tubular stent 106 is to be formed by winding the stent wire itself about the mandrel, and the so-formed tubular stent 106 does not yet have its luminal graft 124 or its outer tape member 128.

Leopold also forms its luminal graft 124 independently from its stent 106. (Leopold, column 11, lines 45-49). Leopold then specifically teaches that its luminal, tubular graft 124 is placed over a mandrel. (Leopold, column 11, lines 9-15). Leopold then teaches that its formed

tubular stent 106 is placed over the tubular graft 124 so that both tubular devices are disposed over this mandrel. (Leopold, column 11, lines 49-53).

Finally, Leopold then wraps its tape member 28 over the exterior portions of the stent 106. (Leopold, column 11, lines 54-57). Leopold then places the mandrel into an oven to form its stent-graft 106. (Leopold, column 11, line 66, to column 12, line 7).

Thus, Leopold independently forms a tubular stent 106 and a tubular luminal graft 124, and its tape member 128 is helically wrapped over these tubular components to form its tubular stent 106. In other words, Leopold clearly fails to teach or suggest, *inter alia*, flat strip assembly of an elongate preformed non-textile planar strip of polymeric graft material and a planar stent.

Moreover, such teachings of Leopold are not only in direct contrast to the present invention, but are also a teaching away from the structural limitations of the subject independent claim. For example, Leopold fails to teach or suggest, *inter alia*, an elongate preformed non-textile planar strip of polymeric graft material, a planar stent attached to the planar graft material to form a flat strip assembly, which is subsequently wound to form the inventive stent graft.

As the Examiner acknowledges that Leopold fails to teach or suggest, *inter alia*, a planar stent assembly, the Examiner applies Lau, in particular FIGS 6, 7, 9 and 10 of Lau. Lau does teach that its stent structure 200, 202 of FIGS. 6 and 7 may be formed from a flat sheet. (Lau, column 13, lines 19-20). Lau, however, specifically teaches that its preformed strips of stent materials are to be wound over a mandrel. (Lau, column 14, lines 42-51). After Lau's strips of stent material are helically wound over a mandrel, then its outer tubular graft or sleeve 217 is slipped over the helically wound stent 214. (Lau, column 14, lines 52-53; FIG. 10). Indeed, Lau specifically teaches throughout its patent that its tubular stent is to be first formed

and then its graft layer is to be placed or formed over the tubular stent. (See, e.g., Lau, column 26, lines 48-58; column 27, lines 21-23; etc.).

Thus, Lau fails to teach or suggest, *inter alia*, flat strip assembly of an elongate preformed non-textile planar strip of polymeric graft material and a planar stent. Indeed, Lau specifically teaches away from the claimed flat strip assembly because Lau requires that a tubular graft or sleeve must be used to form its device. This is not only in direct contrast to the present invention, but is clearly a teaching away from the present invention.

Accordingly, Lau fails to cure the deficiencies of Leopold.

While the examiner alleges that claimed limitation of "said strip assembly being helically wound into a continuous tubular structure" to be a product-by-process limitation with no structural limitations, the examiner under this reasoning simply ignored the claimed structural limitations of independent claim 1. Clearly, Leopold and Lau individually fail to teach or suggest, *inter alia*, flat strip assembly of an elongate preformed non-textile planar strip of polymeric graft material and a planar stent.

In establishing a *prima facie* case of obviousness, the cited references must be considered for the entirety of their teachings. *Bausch & Lomb, Inc. v. Barnes-Hind, Inc.*, 230 U.S.P.Q. 416, 419 (Fed. Cir. 1986). It is impermissible during examination to pick and choose from a reference only so much that supports the alleged rejection. *Id.* It is only through hindsight reconstruction and selective picking and choosing while ignoring divergent teachings does the Examiner attempt to reach the present invention through the combination of Leopold and Lau. It is also well established, however, that hindsight reconstruction of a reference does not present a *prima facie* case of obviousness, and any attempt at hindsight reconstruction using Appellant's disclosure is strictly prohibited. *In re Oetiker*, 24 U.S.P.Q.2d 1443, 1445-46 (Fed.

Cir. 1993). Such hindsight reconstruction by the Examiner is clear as both Leopold and Lau individually fail to teach or suggest a planar stent and graft strip assembly.

Moreover, the Supreme Court addressed the standard for obviousness in its decision of *KSR International Co. v. Teleflex Inc., et al.*, 550 U.S. 389; 127 S.Ct. 1727; 167 L.Ed.2d 705; 82 U.S.P.Q.2d 1385 (2007). In order for an examiner to establish a *prima facie* case of obviousness after *KSR*, some degree of predictability is necessary. (82 U.S.P.Q.2d at 1395-97). *Takeda Chemical Industries Ltd. V. Alphapharm Pty. Ltd.*, 83 USPQ.2d 1169 (Federal Circuit 2007) is a post *KSR* decision in which the Federal Circuit articulated standards for establishing non-obviousness which again includes predictability of success. (83 USPQ.2d at 1176-79). Further, Section 2143.02 (II) of the MPEP states that "Obviousness does not require absolute predictability, however, at least some degree of predictability is required."

Clearly, the disclosures of Leopold and Lau do not provide sufficient predictability or expectation to support a *prima facie* case of obviousness as neither of these references disclose, teach or suggest, *inter alia*, flat strip assembly of an elongate preformed non-textile planar strip of polymeric graft material and a planar stent. As neither of these references disclose, teach or suggest the present invention, the examiner must provide some reasoning with some degree of predictability of success that one of ordinary skill in the art would modify Leopold and Lau in an attempt to arrive at the present invention. The expectation and predictability to arrive art the present invention though Leopold and Lau do not rise to a level that represents a *prima facie* case of obviousness. It is only through impermissible hindsight reconstruction by using the subject application as a roadmap does the examiner attempt to present a *prima facie* case of obviousness.

Moreover, as the inventive stent/graft composite device is formed from a flat planar strip assembly of planar graft material and a planar stent, the resulting device is structurally

improved over the prior art because the assembly components, i.e., planar graft and planar stent, may be more accurately positioned with respect to one and the other and better secured to each other to provide a stent/graft composite device with improved integrity, as described in the Specification at paragraph [00554].

Therefore, Leopold and Lau, individually or in combination, fail to teach or suggest the inventive stent graft, as set forth in independent claim 1 because Leopold and Lau fail to teach or suggest the claimed structural limitations of the claimed invention and fail to teach or suggest the improved tubular device of the present invention so formed from the claimed structural limitations.

Thus, for the reasons set forth herein, claims 1, 3, 6-8, 12 and 13 are patentably distinct from the applied art as set forth by the Examiner in the Final Office Action. Reconsideration and withdrawal of the rejections of claims 1, 3, 6-8, 12 and 13 are respectfully requested.

Respectfully submitted,

/John S. SOPKO, Reg. # 41321/
John S. Sopko
Registration No.: 41,321
Attorney for Appellants

HOFFMANN & BARON, LLP
6900 Jericho Turnpike
Syosset, New York 11791
(973) 331-1700

VIII. Claims Appendix

Claim 1. (Previously presented): A stent/graft composite device formed from a flat preformed planar strip and stent assembly comprising:

an elongate preformed non-textile planar strip of polymeric graft material having a first exterior surface and a second opposed luminal surface; and

a planar stent attached onto one of said opposed flat exterior or luminal surfaces of said strip to form said flat strip assembly, said strip assembly being helically wound into a continuous tubular structure.

Claim 2. (Withdrawn): The device of claim 1 wherein successive helical windings creates an overlap defining a seam between the exterior surface of a first helical wind and the luminal surface of a subsequent helical wind.

Claim 3. (Original): The device of claim 1 wherein successive helical windings do not overlap.

Claim 4. (Withdrawn): The device of claim 1 further comprising a second elongate preformed planar strip of graft material, wherein said stent assembly is positioned between the two planar graft strips.

Claim 5. (Withdrawn): The device of claim 4 wherein said planar graft strips are laminated together to form said strip assembly.

Claim 6. (Original): The device of claim 1 wherein said polymeric graft material is selected from the group consisting of fluoropolymers, polyurethanes, silicones and mixtures thereof.

Claim 7. (Original): The device of claim 1 wherein said polymeric graft material comprises ePTFE.

Claim 8. (Original): The device of claim 1 wherein said tubular structure has a generally circular cross-section.

Claim 9. (Withdrawn): The device of claim 1 wherein said planar stent comprises a plurality of stent wires.

Claim 10. (Withdrawn): The device of claim 1 wherein said planar stent comprises a plurality of linked stent wires.

Claim 11. (Withdrawn): The device of claim 1 wherein said planar stent is comprised of nitinol.

Claim 12. (Original): The device of claim 1 wherein said planar stent comprises at least one planar stent wire.

Claim 13. (Original): The device of claim 1 wherein said planar stent comprises at least one planar ribbon stent.

IX. Evidence Appendix

There were no declarations or other evidence submitted during the prosecution of this application.

X. Related Proceedings Appendix

None

Respectfully Submitted,

/John S. Sopko, Reg. # 41,321/
John S. Sopko
Attorney for Appellant
Registration No. 41,321

HOFMANN & BARON, LLP
6900 Jericho Turnpike
Syosset, NY 11791
(973) 331-1700